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21365 7590 09/20/2007 GEN PROBE INCORPORATED 10210 GENETIC CENTER DRIVE Mail Stop #1 / Patent Dept. SAN DIEGO, CA 92121			EXAMINER RAMDHANIE, BOBBY	
			ART UNIT 1743	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdept@gen-probe.com
kelleec@gen-probe.com
belindao@gen-probe.com

Office Action Summary

Application No.

10/763,449

Applicant(s)

ANDERSON ET AL.

Examiner

Bobby Ramdhanie, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01/23/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :01/23/2007, 12/09/2005, 05/09/2007, & 05/09/2007.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 01/24/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The non-patent literature publication "PACE 2 Specimen Collection Guide" (Gen Probe Incorporated Product Literature, 1996) has not been considered.

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

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The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprising." Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-3, 5, 8-15, 21-23, & 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGregor et al (US4808381). Regarding Claim 1, McGregor et al teaches an automated method for removing a fluid substance from a collection device comprising a fluid-holding vessel and a cap, the method comprising the steps of: A). Puncturing a surface of the cap with a fluid transfer device (Column 4 lines 43-52); C). Continuing movement of the fluid transfer device until the fluid transfer device contacts the fluid substance contained in the vessel (Column 4 lines 55-59); and D). Drawing at least a portion of the fluid substance into the fluid transfer device (Column 4 lines 55-

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59). McGregor et al does not teach Step B). Pausing movement of the fluid transfer device prior to contacting a fluid substance contained in the vessel or E). Removing the fluid transfer device from the collection device. It would have been obvious to one of ordinary skill in the art at the time the invention was made, to modify McGregor et al to include Steps B) and E) because for Step B)., this would allow one to visually confirm that the fluid transfer device passed through the cap before proceeding with the removal of the fluid, and the operator has placed adequate pressure onto the bulb of the fluid transfer device to aspirate the desired amount of fluid from within the vessel and for Step E) to remove the aliquot taken from the vessel.

4. For Claim 2, McGregor et al teaches the method of Claim 1, wherein the fluid substance is obtained from a biological fluid selected from the group consisting of blood, urine, saliva, sputum, mucous, or other bodily secretion, pus, amniotic fluid, cerebrospinal fluid and seminal fluid (Column 2; lines 47-51). It would have been obvious to one skilled in the ordinary art at the time the invention was made to modify McGregor et al to include fluid substances from the group consisting of blood, urine, saliva, sputum, mucous, or other bodily secretion, pus, amniotic fluid, cerebrospinal fluid, and seminal fluid, because although McGregor et al teaches a fluid transfer device for the detection of pathogens from blood, it is common knowledge by those of ordinary skill in art that pathogens are found in a wide variety of bodily fluids and are not limited to blood.

5. For Claim 3, McGregor et al teaches the method of Claim 1, wherein the fluid transfer device is a plastic pipette tip (Column 2 lines 31-33).

6. For Claim 5, McGregor et al teaches the method of Claim 3. McGregor et al does not teach the method of Claim 3 wherein the pipette tip includes one or more grooves recessed from an outer surface thereof, and wherein at least one air passageway is formed between at least one of the grooves and the surface of the cap during Step A). It would have been obvious to one of ordinary skill at the time the invention was made to use a pipette tip that includes one or more grooves recessed from an outer surface thereof, and wherein at least one air passageway is formed between at least one of the grooves and the surface of the cap during step A) because this would have allowed the atmosphere within the container to equilibrate with the atmosphere outside the vessel first, before removal of the liquid or vapor. This would also allow the cap to reseal around the pipette to limit the amount of exposure of the fluid or vapor to the operator.

7. For Claim 8, McGregor et al teaches the method of Claim 1. McGregor et al does not explicitly teach the movement of the fluid transfer device is paused for a period of time sufficient to permit air to vent from within the collection device during Step B). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the movement of the fluid transfer device pause for a period of time sufficient to permit air to vent from within the collection device during Step B) because this would allow the deformable material to re-adjust and maintain a protective seal around the cap after Step B). This would also allow the exposure limit for the operator to be reduced because the barrier of the cap is continually maintained.

8. For Claim 9, McGregor et al teaches the method of Claim 1. McGregor et al does not teach the method of claim 1 wherein the movement of the fluid transfer device is

paused for at least about 0.5 seconds during Step B). It would have been obvious to one skilled in the ordinary art at the time the invention was made to modify McGregor et al to include the movement of the fluid transfer device so it is paused for at least about 0.5 seconds during Step B) because the time to allow the deformable material to readjust and maintain a protective seal around the cap is unknown, predictable, and unreliable.

9. For Claim 10, McGregor et al teaches the method of Claim 1. McGregor et al does not teach that the method of Claim 1, further comprising the withdraw of the fluid transfer device from the punctured surface of the cap between Steps A) and C). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Claim 1 to withdraw the fluid transfer device from the punctured surface of the cap between Steps A) and C) because the cap contains a bi-directional hole which the plastic pipette is inserted into (Figure 1 Item Number 18). As a result if the operator wishes to remove the fluid transfer device, s/he must withdraw the fluid transfer device through the same opening in the cap.

10. For Claim 11, McGregor et al teaches the method of Claim 10. McGregor et al does not teach that the fluid transfer device is paused for at least about 0.5 seconds during step B). It would have been obvious to one skilled in the ordinary art at the time the invention was made to modify McGregor et al to include the movement of the fluid transfer device so it is paused for at least about 0.5 seconds during Step B) because the time that is needed to allow the deformable material to readjust and maintain a protective seal around the cap is indeterminable, unpredictable, and unreliable.

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11. For Claim 12, McGregor et al teaches the method of Claim 1. McGregor et al does not teach the method of Claim 1 wherein the speed of the fluid transfer device during step C) is greater than the speed of the fluid transfer device during step A). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McGregor et al to have the speed of the fluid transfer device during step C) be greater than the speed of the fluid transfer device during step A) because this would also allow the exposure limit for the operator to be at a minimum during Step A during the puncturing of the cap, and minimal exposure of the fluid or aerosol to the operator during Step C.

12. For Claim 13, McGregor et al teaches the method of Claim 12. McGregor et al does not teach the method of Claim 12 further comprising withdrawing the fluid transfer device from the punctured surface of the cap between steps A). and C). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McGregor et al further comprising the withdraw of the fluid transfer device from the punctured surface of the cap between steps A). and C). because this would take into account for pipette that does not actually puncture the cap during initial attempt for penetration, pipettes which bend irreversibly before puncturing the cap, and for pipettes that get jammed midway and cannot fit through the cap.

13. For Claim 14, McGregor et al teaches the method of Claim 12. McGregor et al does not teach the method of Claim 12 wherein the movement of the fluid transfer device is paused for at least about 0.5 seconds during step B). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify

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McGregor et al to include the movement of the fluid transfer device so it is paused for at least about 0.5 seconds during step B) because the time that is needed to allow the deformable material to re-adjust and maintain a protective seal around the cap is indeterminable, unpredictable, and unreliable.

14. For Claim 15, McGregor et al teaches the method according to Claim 14. McGregor et al does not teach the method of Claim 14 further comprising withdrawing the fluid transfer device from the punctured surface of the cap between steps A) and C). It would have been obvious to include in the method of Claim 14 further comprising withdrawing the fluid transfer device from the punctured surface of the cap between steps A) and C) because of jammed pipette or a pipette which is defective and does not keep vacuum when the operator attempts to withdraw the fluid from the vessel.

15. For Claim 21, McGregor et al teaches an automated method for removing a fluid substance from a collection device comprising a fluid-holding vessel and a cap, the method comprising the steps of: a) Contacting a surface of the cap with a fluid transfer device moving at a first speed (Figure 1); b) puncturing the surface of the cap with the fluid transfer device (Figure 1; d) contacting the fluid substance with the fluid transfer device (Figure 2); and e) drawing at least a portion of the fluid substance into the fluid transfer device (Figure 3). McGregor et al does not teach c) entering the collection device with the fluid transfer device moving at a second speed, wherein the second speed is greater than the first speed; or f) removing the fluid transfer device from the collection device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McGregor et al with steps c) and f) because

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steps c) and f) would allow exposure of the fluid or fluid vapor to the operator to be minimized as well as for the removal of pipettes which become defective during the process of removing fluid from the vessel.

16. For Claim 22, McGregor et al teaches the method of Claim 21, wherein the fluid substance is obtained from a biological fluid selected from the group consisting of blood, urine, saliva, sputum, mucous, or other bodily secretion, pus, amniotic fluid, cerebrospinal fluid and seminal fluid (Column 2; lines 47-51). It would have been obvious to one skilled in the ordinary art at the time the invention was made to modify McGregor et al to include fluid substances from the group consisting of blood, urine, saliva, sputum, mucous, or other bodily secretion, pus, amniotic fluid, cerebrospinal fluid, and seminal fluid, because although McGregor et al teaches a fluid transfer device for the detection of pathogens from blood, it is common knowledge by those of ordinary skill in art that pathogens are found in a wide variety of bodily fluids and are not limited to blood.

17. For Claim 23, McGregor et al teaches the method of Claim 1. McGregor et al further teaches the fluid transfer device is a plastic pipette tip (Column 2 lines 31-33).

18. For Claim 25, McGregor et al teaches the method of Claim 23. McGregor et al does not teach the method of Claim 23 wherein the pipette tip includes one or more grooves recessed from an outer surface thereof, and wherein at least one air passageway is formed between at least one of the grooves and the surface of the cap during Step B). It would have been obvious to one of ordinary skill at the time the invention was made to use a pipette tip that includes one or more grooves recessed

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from an outer surface thereof, and wherein at least one air passageway is formed between at least one of the grooves and the surface of the cap during step B) because this would allow the atmosphere within the container to equilibrate with the atmosphere outside the vessel first, before removal of the liquid or vapor. This would also allow the cap to reseal around the pipette to limit the amount of exposure of the fluid or vapor to the operator.

19. Claims 4 & 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGregor et al in view of Roach (US3494201). Regarding Claim 4, McGregor et al teaches the method of Claim 3. McGregor et al does not teach the pipette tip includes one or more ribs extended outwardly from an outer surface thereof, and wherein at least one air passageway is formed between at least one of the grooves and the surface of the cap during Step A). Roach teaches this feature. Roach teaches a pipette with a pipette tip that includes one or more ribs extended outwardly from an outer surface thereof. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a pipette tip that includes one or more ribs extended outwardly from an outer surface thereof extended outwardly from an outer surface thereof, and wherein at least one air passageway is formed between at least one of the grooves and the surface of the cap during Step A) because this would allow air to equalize between the outside of the vessel and the inside and reduce friction of the tip and the cap upon penetration.

20. For Claim 24, McGregor et al teaches the method of Claim 23. McGregor et al does not teach the pipette tip includes one or more ribs extended outwardly from an

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outer surface thereof, and wherein at least one air passageway is formed between at least one of the grooves and the surface of the cap during Step B). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use extended outwardly from an outer surface thereof, and wherein at least one air passageway is formed between at least one of the grooves and the surface of the cap during Step B) because this would allow air to equalize between the outside of the vessel and the inside and reduce friction of the tip and the cap upon penetration.

21. Claims 6 & 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGregor et al in view of Sandhage (US2906423). Regarding Claim 6, McGregor et al teaches the method of Claim 3. McGregor et al does not teach the method of Claim 3 wherein a lubricant is applied to at least a portion of the pipette tip or the surface of the cap prior to step A). Sandhage teaches this feature. Sandhage teaches the application of a lubricant to a plastic pipette tip before insertion through the cap (Column 2 lines 48-52). It would have been obvious to one of ordinary skill at the time the invention was made to modify McGregor et al with Sandhage because according to Sandhage, this application of lubricant would allow for easy insertion of the tip through the cap and also fills up the cut slit thereby preventing the entry of contaminating microorganisms (Column 2 lines 52-57).

22. For Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGregor et al in view of Sandhage (US2906423). McGregor et al teaches the method of Claim 23. McGregor et al does not teach the method of Claim 23 wherein a lubricant is applied to at least a portion of the pipette tip or the surface of the cap prior to step A).

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Sandhage teaches this feature. Sandhage teaches the application of a lubricant to a plastic pipette tip before insertion through the cap (Column 2 lines 48-52). It would have been obvious to one of ordinary skill at the time the invention was made to modify McGregor et al with Sandhage because according to Sandhage, this application of lubricant would allow for easy insertion of the tip through the cap and also fills up the cut slit thereby preventing the entry of contaminating microorganisms (Column 2 lines 52-57).

23. Claims 7, 16-18, & 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGregor et al in view of Koch et al (US5578272). Regarding Claim 7, McGregor et al teaches the method of Claim 3. McGregor et al does not teach the method of Claim 3 wherein the cap includes one or more radially extending ribs positioned on the surface of the cap. Koch et al teaches this feature. Koch et al teaches cap includes one or more radially extending ribs positioned on the surface of the cap (Figure 1, Item Numbers 34-36). It would have been obvious to one of ordinary skill at the time the invention was made to modify McGregor et al with Koch et al because the ribs would allow to more support for tightening and removing the cap from the vessel.

24. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGregor et al in view of Koch et al. For Claim 16, McGregor et al teaches the method of Claim 1. McGregor et al does not teach the method of Claim 1 wherein the surface of the cap punctured in Step A) is a plastic molded in the form of a generally conically inner wall. Koch et al teaches this feature. Koch et al teaches that the cap is plastic that is via a molding process (Column 3 line 53) and that the plastic is molded to have the

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form of a generally conical inner wall (Column 3 lines 53-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McGregor et al with Koch et al because the ribs on the outside wall of the cap would allow for better support when holding the cap and container. Examiner takes the position that the "plastic molded" refers to the cap being made by a molding process.

25. For Claim 17, McGregor et al and Koch et al teach all of the Claim limitations of Claim 16. Koch et al further teaches the cap of Claim 16 wherein the inner wall includes a plurality of radially extended striations (Figure 10 Item numbers 94 & 95). Examiner takes the position that slots 94 & 95, which are made by a blade define striations. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McGregor et al with Koch et al because these slots would reduce the resistance of the cap against the pipette entering through the cap.

26. For Claim 18, McGregor et al teaches all of the claim limitations of Claim 1. McGregor et al does not teach the method of claim 1 wherein the cap contains a wick for limiting the release of an aerosol from the vessel during the penetrating step. Koch et al teaches this feature. Koch et al teaches a cap that is preferably sealed with a wick (Column 4 lines 5-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McGregor et al with Koch et al because it is widely known in the ordinary art that fluids with high vapor pressures, are extremely volatile. Metal sealing foil is commonly used as a barrier for limiting the release of a vapor of an aerosol from a vessel. Examiner takes the position that a wick is any type of

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material that may wipe off or "wick" the outside surface of the pipette used to puncture the seal.

27. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGregor et al in view of Koch et al (US5578272). McGregor et al teaches the method of Claim 23. McGregor et al does not teach the method of Claim 23 wherein the cap includes one or more radially extending ribs positioned on the surface of the cap. Koch et al teaches this feature. Koch et al teaches that the cap includes one or more radially extending ribs positioned on the surface of the cap (Figure 1, Item Numbers 34-36). It would have been obvious to one of ordinary skill at the time the invention was made to modify McGregor et al with Koch et al because the ribs would allow to more support for tightening and removing the cap from the vessel.

28. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGregor et al in view of Koch et al. Regarding Claim 28, McGregor et al teaches the method of Claim 21. McGregor et al does not teach the method of Claim 21 wherein the surface of the cap punctured in Step b) is a plastic molded in the form of a generally conically inner wall. Koch et al teaches this feature. Koch et al teaches that the cap is plastic that is via a molding process (Column 3 line 53) and that the plastic is molded to have the form of a generally conical inner wall (Column 3 lines 53-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McGregor et al with Koch et al because the ribs on the outside wall of the cap would allow for better support when holding the cap and container. Examiner takes the position that the "plastic molded" refers to the cap being made by a molding process.

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29. For Claim 29, McGregor et al and Koch et al teach all of the Claim limitations of Claim 28. Koch et al further teaches the cap of Claim 16 wherein the inner wall includes a plurality of radially extended striations (Figure 10 Item numbers 94 & 95). Examiner takes the position that slots 94 & 95, which are made by a blade define striations. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McGregor et al with Koch et al because these slots would reduce the resistance of the cap against the pipette entering through the cap.

30. For Claim 30, McGregor et al teaches all of the claim limitations of Claim 21. McGregor et al does not teach the method of claim 21 wherein the cap contains a wick for limiting the release of an aerosol from the vessel during the penetrating step. Koch et al teaches this feature. Koch et al teaches a cap that is preferably sealed with a wick (Column 4 lines 5-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McGregor et al with Koch et al because it is widely known in the ordinary art that fluids with high vapor pressures, are extremely volatile. Metal sealing foil is commonly used as a barrier for limiting the release of a vapor of an aerosol from a vessel. Examiner takes the position that a wick is any type of material that may wipe off or "wick" the outside surface of the pipette used to puncture the seal.

31. Claims 19, 20, 31, & 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGregor et al, Koch et al, and in further view of Percarpio (US4338764). Regarding Claim 19, McGregor et al in combination with Koch et al teach all of the claim limitations of Claim 18. McGregor et al and Koch et al, do not teach that

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the wick is selected from the group consisting of pile fabrics, sponges, foams, felts, sliver knits, GORE-TEX® fabrics and spandex. Percarpio teaches this feature. Percarpio teaches a cap comprising a wick within the cap (Column 6 lines 26-31). Examiner takes the position that polytetrafluoroethylene defines a wick. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McGregor et al and Koch et al with Percarpio because according to Percarpio, this material is extremely resistant to hot and cold flow properties and resists attachment of fibrin and red blood cells (Column 6 lines 31-36).

32. For Claim 20, McGregor et al in combination with Koch et al teach all of the claim limitations of Claim 18. McGregor et al and Koch et al do not teach that the wick is maintained within the cap. Percarpio teaches this feature. Percarpio teaches a cap comprising a wick within the cap (Column 6 lines 26-31). Examiner takes the position that polytetrafluoroethylene defines a wick. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McGregor et al and Koch et al with Percarpio because according to Percarpio, this material is extremely resistant to hot and cold flow properties and resists attachment of fibrin and red blood cells (Column 6 lines 31-36).

33. For Claim 31, McGregor et al in combination with Koch et al teach all of the claim limitations of Claim 18. McGregor et al and Koch et al, do not teach that the wick is selected from the group consisting of pile fabrics, sponges, foams, felts, sliver knits, GORE-TEX® fabrics and spandex. Percarpio teaches this feature. Percarpio teaches a cap comprising a wick within the cap (Column 6 lines 26-31). Examiner takes the

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position that polytetrafluoroethylene defines a wick. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McGregor et al and Koch et al with Percarpio because according to Percarpio, this material is extremely resistant to hot and cold flow properties and resists attachment of fibrin and red blood cells (Column 6 lines 31-36).

34. For Claim 32, McGregor et al in combination with Koch et al teach all of the claim limitations of Claim 30. McGregor et al and Koch et al do not teach that the wick is maintained within the cap. Percarpio teaches this feature. Percarpio teaches a cap comprising a wick within the cap (Column 6 lines 26-31). Examiner takes the position that polytetrafluoroethylene defines a wick. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McGregor et al and Koch et al with Percarpio because according to Percarpio, this material is extremely resistant to hot and cold flow properties and resists attachment of fibrin and red blood cells (Column 6 lines 31-36).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 19 & 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitations of a trademark name, renders the

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claim indefinite. Trademark names are subject to change over time and therefore it is unclear what the product being claimed is at any one time. It is requested that this trademark name be deleted from the claim and replaced by generic terminology.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bobby Ramdhanie, Ph.D. whose telephone number is 571-270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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BR


WALTER D. GRIFFIN
SUPERVISORY PATENT EXAMINER